Legislative Analysis

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ALLOW REUSE AND REDISPENSING OF PRESCRIPTION DRUGS

House Bill 6021
Sponsor: Rep. Mike Pumford
Committee: Health Policy

Complete to 6-21-04

A SUMMARY OF HOUSE BILL 6021 AS INTRODUCED 6-16-04

The Public Health Code makes it a misdemeanor offense for any person to sell, dispense, or give away a drug, pharmaceutical preparation, or chemical that had previously been dispensed on prescription and that had left the control of the pharmacist.

The bill would amend the code to allow a pharmacy to accept for resale or redispensing a prescription drug that had been dispensed and that had left the control of the pharmacist if the drug was being returned from a facility that had a registered professional nurse (RPN) or a licensed practical nurse (LPN) who was responsible for the security, handling, and administration of prescription drugs within that facility and if all of the following were met to the satisfaction of the pharmacist:

- The conditions the drug were stored, delivered, and handled before and during its return would not have resulted in damage, deterioration, or contamination so as to adversely affect its identity, strength, quality, purity, stability, integrity, or effectiveness.
- The prescription drug did not leave the control of the RPN or LPN responsible for it and the drug did not come into the physical possession of the individual for whom it was prescribed.
- The labeling and packaging of the drug were accurate; were not altered, defaced, or tampered with; and included the identity, strength, expiration date, and lot number.

This would only apply to a prescription drug dispensed in a unit dose package or unit of issue package.

Before a pharmacy could accept prescription drugs for return, the pharmacist in charge would have to establish a written set of protocols for accepting, returning to stock, repacking, labeling, and redispensing. These protocols would have to be kept on the premises and be readily accessible to each pharmacist on duty. At a minimum, the protocols would have to include the following:

- Methods to ensure that damage, deterioration, or contamination had not occurred that could have adversely affected the strength, quality, purity, stability, integrity, or effectiveness or otherwise have rendered the drugs unfit for distribution.
- Methods for accepting, returning to stock, repackaging, labeling, and redispensing the returned drugs. "Repackaging" would mean a process by which the pharmacy prepared a unit dose package, unit of issue package, or customized patient medication package for immediate dispensing under a current prescription.
- A uniform system of recording and tracking prescription drugs that were returned to stock, repackaged, labeled, and redistributed.

If the integrity of the drug and its package was maintained, a prescription drug returned under the bill would have to be returned to stock and redistributed as follows:

- A prescription drug originally dispensed and returned in the same manufacturer's unit dose package could be returned to stock, repackaged, and redispensed as needed.
- A drug that had been repackaged into a unit dose package or unit of issue package by the pharmacy, dispensed, and then returned to that pharmacy in the same package could be returned to stock, but could not be repackaged. It could only be redispensed in that same unit dose package or unit of issue package and could only be redispensed once. A pharmacist would be prohibited from adding unit dose package drugs to a partially used unit of issue package.

A prescription drug that had been prepared and packaged according to a prescription but did not leave the control of the pharmacist could be returned to stock for redispensing as long as the drug had not expired and had been stored with the original prescription label and in the form in which it was prepared and packaged. A record would have to be made indicating that it had been returned to stock and the return date. The drug would have to be redispensed with a label bearing the same expiration date as the original label unless the drug had been originally dispensed in a unit dose package or unit of issue package and the expiration date was included on that package.

The following could not be returned and redispensed:

- A controlled substance.
- A prescription drug dispensed as part of customized patient medication package. The term refers to a package that was prepared by a pharmacist for a specific patient that contains two or more prescribed solid oral dosage forms.
- A drug not dispensed as a unit dose package or a unit of issue package.
- A drug not properly labeled with the identity, strength, lot number, and expiration date.
- A drug dispensed in a medical institution and returned to stock for redistribution in accordance with departmental rules. The rules define "medical institution" as a state-licensed or approved hospital, skilled nursing facility, county medical care facility, nursing home, or other health facility which directly or indirectly provides or includes pharmacy services.

"Unit dose package" would mean a package that contained single dose drug with the name, strength, control number, and expiration date of that drug on the label. A "unit of issue package" means a package that provided multiple doses of the same drug, but each drug was individually separated and included the name, lot number and expiration date.

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